

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/140,886	08/26/98	WILSON	H N1205-003

ROTHWELL FIGG ERNST & KURZ
SUITE 701-E
555 13TH STREET NW
WASHINGTON DC 20004

HM12/0705

EXAMINER

ZAGHMOUT, O

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/140,886

Applicant(s)

Wilson et al.

Examiner

Ousama Zaghmout

Art Unit

1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/18/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1638

STATUS OF APPLICATION

1. The request filed on 04/18/2001 for Continued Examination (RCA) based on parent Application No. 09/140,886 is acceptable and a CPA has been established. An action on the CPA follows.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The amendment filed 02/20/2001 has been entered (Paper No.14).
4. Status of claims:
Claims 1-22 are pending.

Claim Rejections - 35 U.S.C. § 112

Ist paragraph

1. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, for not satisfying the requirements of the written description. Applicants have not sufficiently described the uncharacterized DNA, nor the plants comprising them, especially as broadly claimed. Hence, it is not clear that Applicants were in possession of the claimed invention since Applicants have not described the plants and Applicants have not disclosed the method of making the plants.

Art Unit: 1638

Because the
"uncharacterized DNA fragments" are not characterized in composition, ^{and} structure ^{they} are not
adequately described. ^{Furthermore} ~~As such~~, the plants are not described either, e.g., in terms of
phenotype, especially for the broad scope of the claims. "Description of a genus may be
achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide
sequence, falling within the scope of the genus or of a recitation of structural features common
to the members of the genus, which features constitute a substantial portion of the genus."
Reagents of the University of California v. Eli Lilly & CO., 119 F3d 1559, 1569, 43 USPQ2d
1398, 1406 (Fed. Cir. 1997).

Weighing all factors, 1) the lack of disclosure of uncharacterized DNA fragments, 2)
the breadth of the claims as reading on genes yet to be discovered, 3) the lack of correlation
between the structure and the function of the genes; in view of the level of knowledge and skill
in the art, one skilled in the art would not recognize from the disclosure that the applicants
were in possession of the genus of DNAs which comprise "uncharacterized DNA fragments".
Therefore, the written description is not satisfied.

Response to arguments:

Applicant's arguments filed 02/20/2001 have been fully considered but they are not
persuasive:

Art Unit: 1638

A. Applicants assert they were in possession of the invention as claimed at the time the instant application was filed. To support their position further, Applicants submit 2 declarations under 37 CFR 1.132, the first by H. M. Wilson and a second declaration by H. H. Stine (stated in Page 2, last paragraph of the Remarks). The Stine Declaration states that methods for the identification of plants with desired traits is described. ^{the} Wilson Declaration provides evidence of the transformation of the reporter gene GUS and uncharacterized sorghum fragment into transgenic plants wherein five of said plants are selected on the herbicide bialaphos. The Wilson Declaration further states that the unsequenced sorghum fragment is located between the GUS and the bar gene (Figure 3), that the transgenic plants are herbicide resistant (Figure 2B) and that the uncharacterized DNA is integrated into the genome as evidenced by genomic Southern blot analysis (Figure 4). This is not found persuasive for a number of reasons:

^{the} First: Stine Declaration is only limited to a general method of selection of plants with desired traits. It does not describe the “uncharacterized DNA fragments” as claimed by the instant application. The Stine Declaration does not disclose the “structural feature which constitutes a substantial portion of the claimed genus”. With respect to the Wilson Declaration, whereas Applicant has described Stine elite Inbred line 963, Applicant has not described the transformed plants as broadly claimed. Furthermore the plants of Stine Elite Inbred Line 963 are not described in the application as filed and are not described in terms of the DNA present in the transformed plants. In the absence of such disclosure, those with skill in the art would not

Art Unit: 1638

recognize that applicants were in possession of the claimed invention at the time when the application was filed.

2. Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention as claimed for the reasons of record mentioned in the previous Office actions.

Applicant's arguments filed 02/20/2001 have been fully considered but they are not persuasive:

A. Applicants assert that the invention is enabled as claimed at the time the instant application was filed. To support their position further, Applicants submit 2 declarations under 37 CFR 1.132, the first by H. M. Wilson and a second declaration by H. H. Stine (stated in Page 2, last paragraph of the Remarks), both summarized above. Applicants further assert that the native regulatory element or elements already present in the donor DNA are sufficient and other heterologous promoters or regulatory elements are not necessary (page 3 of the Remarks). This is not found persuasive for a number of reasons:

First: The Stine Declaration is only limited to a selection of plants with desired traits. Stine does not teach those skilled in the art what DNA fragments to use or not to use. Stine has provided no specific guidance as to how to select genes which will give the desired effect. One wishing to practice the invention is left to proceed through trial-and-error to see what will work

Art Unit: 1638

and what will not. In the Wilson Declaration, the GUS gene and piece of unsequenced DNA fragment do not constitute a substantial portion of the claimed genus. Consequently, this example does not provide specific guidance for those skilled in the art to practice the invention as claimed. Although Applicants are enabled for the Stine Elite Inbred line 963 which has herbicide resistance, Applicants are not enabled for broad claims to plants comprising any uncharacterized DNA with any improved phenotype, and method of making said plants. Undue experimentation would be required to screen through the myriad of transformed plants comprising the vast number of different DNAs to identify those with specific improved phenotypes.

Furthermore, the expression of heterologous and chimeric genes in plants is highly unpredictable and it is unclear whether the gene product from an unidentified and non-exemplified DNA fragment would be expressed at sufficient levels to improve agronomic traits as claimed, since this depends upon appropriate transcription, translation, and post-translational processing and transport of the gene product, and given the degradation of exogenous nucleic acids and proteins in the plant environment.

Second: Since Applicants' invention as claimed entail transforming with "uncharacterized DNA fragments", the invention as claimed would not be enabled if such DNA is not under the control of a regulatory DNA fragment. An improvement in agronomic traits would not be obtained, in the absence of a regulatory DNA fragment, or a coding region. Consequently, undue experimentation ^{would be required} to screen through the fragments of uncharacterized DNA, and plants transformed

Art Unit: 1638

therewith, to identify those that are properly expressed and contain a specific improved agronomic trait.

2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

I. Claims 1, 15 and dependent claims 2-14, 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for the recitation of the phrase “uncharacterized” in the claims as it is not clear what DNA fragments are included or excluded. Hence, the metes and the bounds of the claimed subject matter are not defined in a clear and concise manner.

II. Claims 1, 15 and dependent claims 2-14, 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for the recitation of the phrase “improved agronomic

Art Unit: 1638

characteristic” in the claims as it is not clear how improved ? or what characteristics are included or excluded. Hence, the metes and the bounds of the claimed subject matter are not defined in a clear and concise manner.

III. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being vague. These claims are improperly dependent on Claim 1. It is not clear what method steps are added or modified.

IV. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being vague. These claims are improperly dependent on Claim 15. It is not clear what method steps are added or modified

Claim Rejections - 35 USC § 102

Claims 1-2, 8-9 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Masoud et al [Plant Molecular Biology. 1993. Vol. 21: 655-663] for the reasons of record specified in the previous Office Actions. Applicants assert that amendment of Claim 1 to insert “uncharacterized” overcomes the rejection (Response, P.3). However, the newly added limitation “uncharacterized” still falls within the teaching of the reference. In that respect, the DNA encoding cysteine proteinase inhibitor taught by the reference has not been fully “characterized” to show the intron or other regulatory regions for example. As such, the DNA encoding cysteine proteinase taught by the reference is “uncharacterized”.

Claim Rejections - 35 USC § 103

Art Unit: 1638

Claims 1-22 remain rejected under 35 U.S.C. § 103 as being unpatentable over Masoud et al [Plant Molecular Biology. 1993. Vol. 21: 655-663] in view of Hamilton et al [Proc Natl Acad Sci U S A. 1996 Sep 3;93(18):9975-9979] for the reasons of record specified in the previous Office actions. Applicants assert that amendment of Claim 1 to insert "uncharacterized" overcomes the rejection (Response, P.3). However, the newly added limitation "uncharacterized" in Claims 1 and 15 still falls within the teaching of the reference. In that respect, the DNA encoding cysteine proteinase inhibitor taught by the reference has not been fully "characterized" to show the intron or other regulatory regions for example. As such, the DNA encoding cysteine proteinase taught by the reference is "uncharacterized".

Conclusion

No Claims are allowed.

Art Unit: 1638

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell Ph.D., can be reached on (703) 308-4310. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

June 21, 2001

A handwritten signature in cursive script, appearing to read "Amy Nelson".

**AMY J. NELSON, PH.D
PRIMARY EXAMINER**